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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,494	10/07/2003	Lawrence J. Mulligan	P0011354.00	5535

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EXAMINER	
LAVERT, NICOLE F	
ART UNIT	**PAPER NUMBER**
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/680,494	**Applicant(s)** MULLIGAN ET AL.
	Examiner NICOLE F. LAVERT	**Art Unit** 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2009*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-22* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *07 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date *4/25/06 & 2/14/05*.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. **Claims 1-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Deno et al (US 2003/0074029) in view of Bennett et al. (US 5,231,098).

Deno et al. discloses an apparatus and method for monitoring and/or optimizing the delivery of an extra-systolic stimulation (ESS) therapy for a plurality of extra-systolic intervals (ESIs) comprising; setting a test ESI for delivery of an ESS therapy; applying the ESS therapy at the test ESI; determining and calculating: a baseline contractile function parameter during and after the delivery of the ESS therapy (e.g., [0019]-[0022] & [0083]-[0086]), and determining a potentiation ratio (PR) and a recirculation factor (RF), based on said contractile function parameter, wherein an optimal ESI is determined via incrementing and/or decrementing the test ESI within a predetermined range of values (e.g., [0091]-[0098] & [0123]-[0134]).

Deno et al. discloses the claimed invention having an apparatus for monitoring and/or optimizing the delivery of ESS therapy except wherein said apparatus and method further comprise calculating a maximum product of RF and PR for each test ESI so as to determine the optimal ESI. Bennett et al. teaches that it is known to use an automatic cardiac stimulator capable of enhancing and/or optimizing cardiac performance by way of providing post extrasystolic potentiation (PESP) stimulation via utilizing sensed baseline cardiac stress index (CSI) and cardiac performance index (CPI) variables in an optimization algorithm, in which both the CSI and CPI variables correspond to the optimization of an ESI [e.g., (col 5, ln 53-65) & (col 7, ln 1-43)], wherein the operating ESI may be automatically adjusted, incrementally and/or decrementally, by way of the continual optimizations of the CSI and CPI variables [e.g., (col 17, ln 34-67) & (col 18, ln 23-66)]. Note that the Examiner is interpreting the sensed baseline data representing the average values of CSI and CPI variables as being analogous to the determined potentiation ratio (PR) and recirculation factor (RF) as is instantly claimed (e.g., col 17, ln 34-45). Also note that it well known that the disclosed optimization algorithm may utilize the product of the CSI and CPI variables, as is instantly claimed, in order to optimize the PESP stimulation of a patient's heart [e.g., (col 5, ln 53-65) & (col 7, ln 1-43)]. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus as taught by Deno et al. with the method and apparatus for optimizing PESP stimulation via utilizing an optimizing algorithm, in which calculates the optimized stimulation based on averaged-CSI and CPI variables, as taught by Bennett et al., since such a modification would provide the apparatus for monitoring and/or optimizing the delivery of ESS therapy by calculating a maximum product of RF and PR for each test ESI so as to determine the optimal ESI for providing the predictable results pertaining to calculating an effective ESI so as to provide post-extrasystolic potentiation cardiac output augmentation by providing calculated and triggered pacing stimulation specifically timed (e.g., Bennett, col 4, ln 41-65).

Response to Arguments

4. Applicant's arguments filed 6 October 2006 have been fully considered but they are not persuasive. The Applicant argues that the primary reference, Deno et al., fails to disclose the determination of a potentiation ratio (PR), and therefore it is unreasonable to interpret Deno et al. to teach or suggest determining a product of a potentiation factor (PR) and a recirculation factor (RF). In addition, the Applicant also argues that the assertion that the secondary reference, Bennett et al., teaches utilizing a product of CSI and CPI variable is simply untrue since Bennett et al. does not disclose computing a product of the CSI and CPI variables in order to control the disclosed PESP stimulation. The Examiner disagrees and further points out that the Applicant defines the PR to be the ratio of the following parameters:

> "…parameter indicative of myocardial contractile function on a pre-extra systolic beat(s) and on a post-extra systolic beat(s)…"

In view of the above definition provided by the Applicant, the Examiner interprets the disclosed heart failure parameter of the systolic, developed pressure, dP/dt, to be "indicative" of the claimed myocardial contractile function [e.g., 0006], in which the dP/dt (MAX) and (MIN) determined within a referenced steady state (SS) paced heart cycle (i.e. parameter on a pre-extra systolic beat(s)) and the dP/dt (MAX) and (MIN) determined within an extrasystolic pulse (ES) (i.e. parameter on a post-extra systolic beat) and normalized with respect to one another as being the determined potentiation ratio instantly claimed (e.g., Deno, [0020] & [0092]-[0098]) used in order to strengthen the cardiac contraction via PESP stimulation when one or more parameters show that the heart condition has progressed to benefit from increased contractility, etc., [e.g., 0020]. In addition, the Examiner also notes that the disclosed CSI and CPI variables are variables that control the frequency of PESP stimulation and are further employed in the disclosed optimization algorithm for PESP stimulation (e.g., col 7, ln 1-43) in which, as the Examiner stated in the last office action, it is well known in the art that the disclosed optimization algorithm may use the product of the CSI and CPI variables in order to determine the sensor-controlled PESP feature. Therefore Deno et al. in view of Bennett et al. disclosed the claimed invention.

5. Applicant's arguments, filed 10/6/09, with respect to the 112, second paragraph claim rejection have been fully considered and are persuasive and have been withdrawn.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Nicole F. LaVert/
Examiner, Art Unit 3762